IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
(SHERMAN DIVISION)

ROZLYN ACKERMANN, Individually and as Personal Representative of the Estate of MARTIN LINDSEY ACKERMANN, Deceased, Plaintiff,	§	
v.	§	CASE # 4:05-cv-00084-MHS-DDB
WYETH PHARMACEUTICALS, Defendant.	§	

PLAINTIFF'S RESPONSE AND MEMORANDUM IN OPPOSITION TO WYETH'S MOTION FOR SUMMARY JUDGMENT
(STATE LAW)

Respectfully submitted,

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Wyeth raises seven bases for summary judgment, ostensibly under state law. For the following reasons, and on the following authorities, with the exception of the fraud and misrepresentation theories, the remainder of Wyeth's motion should be denied.

STATEMENT OF GENUINE ISSUES

In accordance with Local Rule CV-56, the following disputed material issues of fact require a trial by jury and preclude summary judgment in this case:

-- Whether Wyeth ever gave any warning, much less a legally adequate warning, about Effexor-induced suicidality or its precursors?

-- Whether Wyeth ever gave appropriate instructions to ameliorate the risk of suicidality and/or its precursors

-- Whether any such warnings or instructions were effectively communicated to Dr. Sonn, as Texas law clearly requires?

-- Whether Dr. Sonn would, or would not, have heeded a legally adequate warning and appropriate instructions, effectively communicated?

-- Whether there is evidence that Wyeth has withheld from the FDA material information about the risk of Effexor-induced suicidality?

The remaining alleged bases for summary judgment are purely legal, and, thus, beyond the ambit of the Local Rule's requirements.

ARGUMENT AND AUTHORITIES

I. THE "LEARNED INTERMEDIARY" DOCTRINE DOES NOT WARRANT SUMMARY JUDGMENT IN THIS CASE

A. Wyeth Fails to Plead or Prove that It Gave a Legally Adequate Warning About Effexor-Induced Suicidality. Unquestionably, the "learned intermediary" doctrine is recognized under Texas law. *See Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999); *Alm v. Aluminum Co. Of America*, 717 S.W.2d 588, 591-92 (Tex. 1986) and cases cited therein. Under this doctrine, the drug maker is exonerated for tort liability for failure to warn if, but only if, it has provided a legally adequate warning. *See In re Norplant Contraceptive Products Liability Litigation*,

955 F.Supp. 700, 704, citing *Bristol-Myers Co. V. Gonzales,* 561 S.W.2d 801 (Tex. 1978) and *Crocker v. Winthrop*, 514 S.W.2d 429 (Tex. 1974), and the subsequent 122-page tome by Chief Judge Schell at *In re Norplant Contraceptive Products Liability Litigation*, 215 F.Supp.2d 795 (E.D.Tex., 2002).

However, "[p]hysicians become learned intermediaries only when they have received adequate warnings from the drug manufacturer." *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003). Thus, in this case, as in *Tobin v. Smithkline Beecham*, Civ. No. 00-CV-0025-Bea (D.Wyo. April 12, 2001)(unpublished opinion attached as Exhibit A)[1] "[t]he defendant does not argue in its motion for summary judgment that the warnings to Dr. [Sonn] regarding [Effexor] were legally adequate. In that regard, the learned intermediary doctrine would not directly apply since the defendant has not attempted to demonstrate that it provided the prescribing physician with a sufficiently clear warning."

Therefore, this Court should conclude, as did Judge Beaman in *Tobin*, that "[d]ue to the absence of any arguments as to the adequacy of the warnings regarding [Effexor] induced violence, manic shifts, psychotic breaks, and suicide this Court finds the adequacy of the warnings a material fact to be decided by the jury." *Id*. at p. 14, citing *Garside v. Osco Drug, Inc.,* 976 F.2d 77 (1st Cir.1992), discussed *infra*.

B. Wyeth Also Fails to Allege and Prove that Dr. Sonn Knew All of the Pertinent Information about Effexor-Induced Suicidality, or that He Would Have Failed to Heed a Legally Adequate Warning *from* Wyeth Itself. Not surprisingly, Wyeth focuses on snippets from the favorable deposition testimony it secured from Dr. Sonn, the physician who prescribed Effexor

[1] This citation is to the unpublished pretrial order denying summary judgment on the basis of the "learned intermediary" doctrine. The court's post-verdict opinion in this Paxil-induced homicide/suicide case, denying SmithKline's motion for new trial is reported at *Tobin v. SmithKline Beecham Pharmaceuticals*, 164 F.Supp.2d 1278, 1284 (D.Wy. 2001).

to Martin Ackermann. As we point out in subsection C, *infra*, the case law concerning the applicability of the comment *j* "read and heed" presumption is conflicting. Plaintiff believes that the better reasoned view is (1) that this presumption does apply to a "learned intermediary," (2) it switches the burden of proof on causation, and (3) the focal point of inquiry is an objective one, *i.e.*, what a "reasonably objective" physician would have done with a legally adequate warning rather than on what the actual prescribing physician – who might be impaired by bias, fear of suit, guilt, or other motivation, says he/she would have done with such a warning. However, in this section we assume, *arguendo* that the Court rejects our arguments in this regard and focuses solely on what the record from Dr. Sonn himself shows. Because the record in this case does not begin to rise to the level of summary judgment proof required, even under the more pro-defendant interpretation of the law, the Court need not struggle with the more arcane refinements of the law regarding comment *j*.

Although the question of the adequacy of warning and the related question of what the prescribing physician would have done with a legally adequate warning are generally questions of fact, in some circumstances the facts are truly undisputed enough to warrant summary judgment as a matter of law. There are a handful of cases across the country in which this has occurred. In *Garside v. Osco Drug, Inc.,* 976 F.2d 77 (1st Cir.1992) the First Circuit focused on the common denominator in each of these cases, summing them up with the following succinct observation:

> "In all such cases, courts have required that the physician's testimony show unequivocally that s/he knew at the relevant time *all* the information which would have been included in a proper warning." *Id*. at 82 (emphasis in original).

Chief Judge Schell's decision granting summary judgment for the drug maker in *In re Norplant, supra*, is illustrative of the circumstances in which summary judgment may be granted and sustained: "[a]ll five of the prescribing physicians testified **unequivocally** . . ." 955 F.Supp. at 710.

One of the cases in which summary judgment was granted is the Prozac-induced suicide case of *Woulfe v. Eli Lilly*, 956 F.Supp. 1478 (E.D.Okla. 1997).[2] Juxtaposition of the record facts in *Woulfe* with those in the case at bar illustrate the inappropriateness of summary judgment in this case. In *Woulfe*, Dr. Newey testified from extensive records and a long standing personal and professional relationship with Mr. Woulfe. By contrast, Dr. Sonn, who keeps no records whatsoever, only saw Martin Ackermann four times in an eight-day period of his life. Exhibit B at p. 66. (Sonn deposition). In *Woulfe*, Dr. Newey was asked directly whether or not he would have heeded Eli Lilly's German warning about Prozac and suicide.[3] In the case at bar, the only questions addressed to Dr. Sonn were about the changes in his medication practices in light of the FDA mandated regulatory warnings over the past couple of years. (Even at that, his answers were quite equivocal, as illustrated *infra*.) For obvious tactical reasons, Wyeth's counsel never asked the critical hypothetical question that would be the necessary foundation for summary judgment:

> Q: "Dr. Sonn, if my client had issued a prominent warning to caution you that, in a 'small vulnerable sub-population' of patients, Effexor can trigger suicide, and had "brought home" that warning to you via (i) bold faced or 'black boxed" wording in the package insert, (ii) a "Dear Doctor" letter, and/or (iii) visits from your Wyeth sales representative, would you have (a) heeded that warning, or (b) ignored it?"

There is a critical distinction between a "no warnings" case and an "inadequate warnings" case. As the pleadings and record in this case show, prior to Martin Ackermann's death, Wyeth

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[2] Counsel for plaintiff in this case was also lead counsel for the Woulfe children. The case was appealed, *inter alia*, to give the Tenth Circuit a chance to rule on the burden switching and objective/subjective issues raised by *Wooderson* and similar cases. Unfortunately – from the standpoint of the development of the law – the case was settled before those issues could be addressed and the appeal was, accordingly, dismissed.

[3] In retrospect, this was undoubtedly a tactical error by counsel. Although the German warning was issued by Lilly itself, and was specifically addressed to the question of Prozac induced suicidality and the steps that can be taken to ameliorate that risk, it was certainly not the strongest warning possible. The adequacy *vel non* of a particular warning is a jury question, and it is important to remember that it is the defendant who bears the legal burden of promulgating an adequate warning. The plaintiff has no burden to write that warning for them.

issued no warning whatsoever about Effexor induced suicidality. Even today, Wyeth refuses to acknowledge that Effexor can actually cause suicide in adult patients and has failed to warn about same.

Thus, the question for the jury in this case is not what Dr. Sonn did or did not do in the face of no warnings, and, with respect, not even what he would or would not do now with inadequate, "minimum standards" warnings required by the FDA. Rather, as the hypothetical question phrased above indicates, the question becomes what would he have done with a legally adequate warning, effectively communicated?

Interesting, his testimony shows precisely what he does when he is provided with such warnings. The ADHD drug Ritalin carries a "BLACK BOX" warning about the risk of psychosis. Exhibit C. Dr. Sonn admitted that, even though he has never had a patient who became psychotic on Ritalin, he still warns his patients about that risk.[4] This is extremely germane in this case because one of the biologically plausible pathways or "antecedent" conditions triggered by Effexor and which, in turn, trigger suicidality, is drug-induced psychosis. It is, in fact, the precise mechanism of action which is most accountable for Martin Ackermann's death. Exhibit D at pp. 290, 324 (excerpts from deposition of Plaintiff's expert, Dr. David Healy).

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[4] It should be noted that, even if the Court rejects the "burden flipping" arguments and authorities in subsection C, Plaintiff still does not bear the burden of proving that, with an adequate warning, the prescribing physician would have refused to prescribe the drug. That is because the law in Texas as elsewhere is that a product maker must not only provide warnings about the risks inherent in his product, but also instructions for ways to ameliorate that risk. See Tex PJI 71.5. There are many ways that the risk of Effexor induced suicidality can be ameliorated other than non-prescription. They include (a) careful monitoring and (b) concomitant antidotes for the SSRI induced precursors to suicidality, as embodied in the German Prozac warnings at issue in *Woulfe*. They also include words of caution to the patient and family, which is what Dr. Sonn does with his Ritalin patients. Finally, they include tapering of the drug.

The only authority for the proposition that a plaintiff bears the burden to prove that the doctor would not prescribe the drug is Restatement (Third) section 6(c) which imposes such a burden for a design defect case. Because it is neither founded on existing case law, nor consistent with the underlying rationale for strict products liability, several courts have already rejected this section.

In the context of a summary judgment motion, all inferences are to be resolved against the movant. There is a clear and strong inference that, if Dr. Sonn heeded one drug maker's warning about drug-induced psychosis, he would, likewise, have heeded a similar warning from Wyeth about Effexor-induced psychosis. This, in and of itself precludes summary judgment.

However, there is more. The complete deposition of Dr. Sonn – which Wyeth failed to list as an exhibit but which we have attached as Exhibit B, shows that he was and still is woefully "unlearned" about the risks of Effexor-induced suicidality. At first blush, Wyeth's list of all of the things of which Dr. Sonn was aware, at the time he prescribed Effexor for Martin Ackermann (Wyeth brief at pp. 12-13) looks impressive. So, too, is his testimony about what he would or would not do now, given his current knowledge.

But Wyeth has a problem here. A huge problem. Nowhere in this list is there anything to indicate that Dr. Sonn was then or is now aware that "Wyeth concedes that Effexor can trigger suicidality for some patients." **That** is what a legally adequate warning, from Wyeth, would have told him. Nothing in this record demonstrates that Dr. Sonn was aware of "all the information that would have been included in a proper warning" as the host of cases cited in *Garside* and its progeny requires.

Moreover, it is significant that in *Woulfe* the court was also extremely concerned as to whether there was any equivocation in the prescribing physician's testimony and whether she/he had credibility problems. The court wrote that "[t]he weight to be afforded such affidavit or testimony, however, depends on the substance of the evidence as well as the credibility and reliability of the treating physician himself. In the instant case, Plaintiff has offered absolutely nothing to call in to question either the substance of Newey's affidavit or his credibility with respect to the statements he makes."

Not so with Dr. Sonn. Regarding Dr. Sonn's prescribing practices, here's what radio personality Paul Harvey calls *the rest of the story.*

An overdose of pro-Wyeth, anti-Ackermann bias: Dr. Sonn self-medicates with Effexor. "I had an episode of depression in 1997 and I take Effexor myself and so I use the samples."[5] He went on to state, "I take 225 milligrams a day. I've been taking that for more than five years and I think it's a lifetime thing for me."[6] One just might think that having a permanent condition and being the beneficiary of *gratis* medication for it just *might* affect one's objectivity.

But there's more.

When Dr. Sonn received a request for his records on Martin Ackermann, he reacted by notifying his malpractice carrier and obtaining the services of an attorney.[7] When reminded that no allegations had been made against him in this case, Dr. Sonn stated, "I still–it still doesn't make me like this process any more."[8] He also remarked gratuitously, "I'm generally not a fan of Plaintiff attorneys who bring these kind of suits."[9]

Before his deposition, Dr. Sonn had never met with Mrs. Ackermann's attorneys–but he had considerable communication with Wyeth's. On two occasions, he'd spoken with defense counsel,

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[5] Sonn deposition, p. 9.

[6] Sonn deposition, p. 19.

[7] Sonn deposition, pp. 75,76.

[8] Sonn deposition, p. 182.

[9] Sonn deposition, p. 162.

and he met with them for an hour before his deposition.[10] Additionally, during multiple breaks during his deposition he consulted with Wyeth's counsel.[11]

Before the Court considers dismissing Mrs. Ackermann's case based on the testimony of Dr. Sonn, she would ask that it seriously consider the fact that he is far from an objective witness in this proceeding and that his deposition testimony revealed that he was saturated with bias.

Dr. Sonn passes on "black box" warnings: When he prescribes medicine for his patients, Dr. Sonn testified that what he *usually* does is ". . . hand them a box that has this in it, has some directions inside."[12] He said that before prescribing a drug he would review the *Physician's Desk Reference*, "But I would be primarily interested in the side effects, the warnings."[13] For example, he testified that he prescribes Ritalin from time to time. As noted above, Ritalin has a black box warning that includes psychosis. Even though he's never had a patient become psychotic while taking Ritalin, he still warns them about this side effect because it's within the black box.[14] He also stated that, "I mean, if–if it's black boxed and indicated, then you would do it."[15] Then, this 72-year-old semi-retired psychiatrist testified that if required to do so by law, he would give a black box warning, and if not, would simply balance the risks and benefits of the drug, however, ". . . I would–it would have to be approached differently now. And on the basis of this experience, at my

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[10] Sonn deposition, pp. 58, 59.

[11] Sonn deposition, p. 160.

[12] Sonn deposition, p. 22.

[13] Sonn deposition, p. 42.

[14] Sonn deposition, p. 184.

[15] Sonn deposition, p. 125.

age, I don't know whether I might not refer somebody to another physician."[16] Finally, when asked *again* if he would give a black box warning "if there was no legal requirement" to do so, Dr. Sonn said:

> "Now, if somebody says, 'Do you have to tell them that they may have diarrhea with this if they have a black box,' then I'm going to tell them that they have diarrhea. Otherwise, I would not–I would include that under the physical side of taking a drug."[17]

How reliable is Dr. Sonn's testimony about Martin Ackermann anyhow? Dr. Sonn saw Martin Ackermann in January of 2002. After just a few visits, Marty fired him. Dr. Sonn has no notes of his sessions with Marty. He keeps no records on any of his patients.[18] Dr. Sonn estimated that he sees patients at the rate of 800 office visits per year. His deposition was taken nearly four years—or 3,200 office visits later—and he had no records to refresh his memory about Martin Ackermann.[19] Yet he testified for hours about Marty's condition, conversations between him and the patient, conversations between him and the referring partner from Gardere, Wynne & Sewell, side effects of the medication that Marty had been experiencing, symptoms he had, symptoms he *didn't* have, etc. All of this about two office visits, four years, and 3,200 patients later.

Incredible.

The bottom line regarding Dr. Sonn's testimony is this: despite his curiously cozy relationship with the Wyeth lawyers, and despite his admitted hostility towards this case and the undersigned plaintiffs' lawyer, and despite the fact that Wyeth subsidizes his health care with free pharmaceuticals, and despite his unquestioned loyalty to and preference for Effexor, he heeds black

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[16] Sonn deposition, p. 126.

[17] Sonn deposition, p. 127.

[18] Sonn deposition, p. 169.

[19] Sonn deposition, p. 177.

box warnings. Had suicide warnings been included in the sample box of Effexor "with the directions inside" he'd given to Martin Ackermann, there's little doubt that Marty would have been forewarned.

C. Wyeth Ignores the Burden of Proof and the Comment *j* Heeding Presumption.

Under comment *j* to Restatement section 402A, a product manufacturer benefits from a presumption that their legally adequate warning would and should have been heeded by the user of the product. But in Texas, as in a number of other states, the courts have construed comment *j* to provide a corollary presumption in favor of the plaintiff in a "no warning" case like this. *Reyes v. Wyeth Laboratories,* 498 F.2d 1264, 1281 (5th Cir.). It is usually labeled as a "heeding presumption," and, in operation, the law presumes that the consumer, or, in the case of a pharmaceutical product, the "learned intermediary," would have heeded an adequate warning IF such a warning had been given.

One of the best reasoned comment *j* "learned intermediary" opinions in this country, was authored by the Kansas Supreme Court. In *Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 681 P.2d 1038(Kan. 1984), it held that the effect of the presumption in a no warnings, pharmaceutical case is to shift the burden of proof on causation to the defendant:

> "Comment *j* provides a **presumption** that an adequate warning would be heeded. This operates to the benefits of a manufacturer where adequate warnings in fact are given. **Where warnings are inadequate, however, the presumption is in essence a presumption of causation." . . . "`What the doctor might or might not have done had he been adequately warned is not an element plaintiff must prove as a part of her case.**' . . . The evidence provided by Dr. Froelich as to his independently acquired knowledge is insufficient to rebut the presumption established by Comment *j*."

Id. at 1057 (emphasis added; citations omitted). *Accord, Tobin, supra* at p. 18.

No Texas state court has either accepted or rejected the "heeding presumption" in a "learned intermediary" context. However, the *Erie* predictions of federal district courts have split on the issue

with the Southern District going one way, and the Northern another. *Compare Anderson v. Sandoz Pharmaceuticals Corp.*, 77 F.Supp.2d 804 (S.D.Tex. 1999), *with Koenig v. The Purdue Pharma Co.,* 2006 WL 1489250 (N.D.Tex. May 25, 2006). Because the heeding presumption is perfectly consistent with the traditional rationale for strict liability, the best *Erie* prediction that this Court can make is that the Texas courts will embrace it, even in a learned intermediary context.

A corollary of the presumption in many states is that, even if it does not switch the burden of proof entirely, the focal point for rebutting the presumption is not the subjective state of mind of the actual prescribing physician, but rather the "reasonably objective" independent physician. "To satisfy the burden of establishing warning causation, a plaintiff may introduce either objective evidence of how a reasonable physician would have responded to an adequate warning, or subjective evidence of how the treating physician would have responded." *Thomas v. Hoffman-LaRoche, Inc*. 949 F.2d 806, 812 (5th Cir. 1992). *Accord Hermes v. Pfizer, Inc.*, 848 F.2d 66, 69-70 (5th Cir.1988). *See also Cunningham v. Charles Pfizer & Co., Inc.,* 532 P.2d 1377 (Okla. 1975). Because there is no proof that any reasonably objective physician would have ignored a clear warning from Wyeth about Effexor-induced suicidality, summary judgment is inappropriate.

D. <u>Wyeth's "Overpromotion" of Effexor Negates the "Learned Intermediary" Doctrine.</u> The learned intermediary doctrine is a common law affirmative defense. The courts which have accepted, or created, that defense have, likewise, recognized several exceptions to the defense. One of these is "overpromotion."[20] *Vitanza v. The Upjohn Co.*, 778 A.2d 829, 847 (Conn. 2001), citing *Proctor v. Davis*, 291 Ill. App. 3d 265, 279-84, 682 N.E.2d 1203, 225 Ill. Dec. 127, cert. denied, 175 Ill. 2d 553, 689 N.E.2d 1146, 228 Ill. Dec. 725 (1997). Although no Texas court,

[20] Another is "direct to consumer" advertising. *Id*. citing *Perez v. Wyeth Laboratories, Inc.*, 161 N.J. 1, 21, 734 A.2d 1245 (1999). Because it is not necessary to defeat summary judgment, we will not belabor the Court with evidence about Wyeth's direct to consumer advertizing of Effexor.

or even federal court applying Texas law, has decided the issue, the best *Erie* guess is that the Texas courts will follow the common law majority and embrace this exception as well.

There is very little case law telling us what overpromotion is, and what it is not. Surely promotion for "off-label" uses (which is not here alleged) would suffice. So, too, would promotional activities which were false or misleading. The evidence in this case shows that in the years before Effexor was prescribed to Martin Ackermann, Wyeth sales representatives were using standardized sales pitches which they subsequently had to withdraw because the FDA chided them for being misleading. Exhibit E (deposition of Wyeth sales representative Amy Court - FILED UNDER SEAL) and Exhibits F and G to that deposition.[21] *See* Exhibit H, Rule 56(e) Affidavit of Counsel regarding unavailability of additional evidence due to on-going discovery in a related case. This, too, undermines Wyeth's reliance on the learned intermediary doctrine.

Wyeth will undoubtedly argue, "but there is no proof that any deceptive or misleading promotional materials were shared with Dr. Sonn, or that he was influenced in any way by them." Admittedly, such proof would make the argument more persuasive, but, from a summary judgment context, the inferences must be drawn against Wyeth. Moreover, the courts which have applied this doctrine to negate a drug maker's reliance on warnings have noted that the influences of such promotional activities are frequently very subtle and that the effects on the prescribing physician may even be subconscious.

II. SECTION 82.007 DOES NOT JUSTIFY SUMMARY JUDGMENT IN THIS CASE

In September 2004 a bill known as H.B. 4, and promoted as a "tort reform" measure, passed the Legislature and was enacted into law. It is codified into the Civil Practice and Remedies Code.

[21] One of the exhibits to that deposition is being filed under seal because of Wyeth's confidentiality designation. However, we have been careful not to quote any material in the body of this Brief that has been designated by Wyeth's counsel as confidential.

One of the provisions of that bill is a statutory presumption of "no marketing defect" for a drug which carries a FDA approved label. § 82.007(a), Tex.Civ.Pract. & Rem. Code. The presumption is rebuttable in nature. One of the ways to rebut it is by showing that the drug maker withheld material information from the FDA. §82.007(b)(1).

Wyeth makes two principal arguments in this section of its brief. The first is that *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001) preempts §82.007(b)(1), without touching the pro-defendant provisions of sub-section (a). The second, which it makes in one brief paragraph, is that there is no evidence in this case of such withholding.

This legal issue has been languishing around in this case since the first Rule 16 conference before Judge Clark. In that conference, Wyeth's counsel raised the spectre of 82.007 and told the judge that, in their view, *Buckman* preempted the exception, but not the rule. The Court instantly recognized the distinction between evidence supporting a "cause of action" and evidence proffered for another purpose, *i.e.*, to rebut a statutory defense.[22] It is a distinction which has been lost on Wyeth's counsel.

A. *Buckman* Does Not Apply to §82.007(b)(1). Wyeth's main argument is that *Buckman* preempts subsection (b)(1). The threshhold issue that the Court must confront is whether *Buckman* is a rule of federal law that preempts an asserted cause of action, or, conversely, whether it must be read as a broad sweeping evidentiary rule of exclusion. The actual holding of *Buckman* is clear, *i.e.*, that the FDCA preempts a state law "fraud-on-the-FDA cause of action."

HB 4 was enacted several years after the *Buckman* decision. There is a presumption that the Legislature was aware of *Buckman* and that it tried to word its enactment so as to avoid federal

[22] The transcript of that hearing is not accessible via Pacer and our calls to the court reporter for same have been unavailing. We therefore respectfully ask the Court to take judicial notice of its own files, and to review the transcript of that hearing on its own.

preemption. Therefore, unless this Court can conclude as a matter of federal law, that *Buckman* must be read, not only to preempt a cause of action, but also to preclude evidence from being introduced in support of other state law causes of action, then sub-section (b)(1) cannot be preempted.

Defendant relies on a trilogy of post-*Buckman* cases to argue that federal law preempts TEX.CIV.PRAC.&REM.CODE §82.007(b)(1). To properly understand the holdings in these cases and why they do not dictate the result Defendant seeks under Texas law, we must examine them in context.

The basis of the plaintiff's claim in *Buckman* was that the manufacturer of defective orthopedic bone screws had made fraudulent representations to the FDA. "Under the plaintiff's theory, had the defendant, a regulatory consultant retained by the manufacturer of the bone screws, not misrepresented certain material facts to the FDA, the FDA would not have approved the screws, and the plaintiff would not have been injured. *Kobar v. Novartis Corp*., 378 F.Supp.2d 1166, 1169 (D. Ariz. 2005)(citing *Buckman*, 531 U.S. at 343)[underlining added]. The Supreme Court held that "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law. 531 U.S. at 343. The holding of *Buckman* is a narrow one, preempting claims that "exist solely by virtue of the FDCA disclosure requirements." *Id.* at 353.

When the Sixth Circuit decided *Garcia*, it faced a Michigan statute that "immunizes drug manufacturers from liability," 385 F.3d. at 963, unless the manufacturer "[i]ntentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug and cosmetic act [citations omitted], and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5)(a)[underlining added]. As the underlining

emphasizes, the Michigan statute expressly contains the critical element of reliance by the FDA. There is no hint of this element in TEX.CIV.PRAC. & REM. CODE §82.007(b)(1). In essence, the Michigan statute expressly codifies a fraud-on-the-FDA theory. Faced with that reality and with the holding in *Buckman*, both the parties and the court in *Garcia* acknowledged that the exception was preempted, and turned to the constitutional questions. *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961 (6th Cir.2004). *Henderson v. Merck & Co.*, 2005 WL 2600220 (E.D. Pa. 2005), faced the same Michigan statute, and also concluded that federal law preempts a state court determination of a fraud-on-the-FDA cause of action.

TEX.CIV.PRAC.&REM.CODE §82.007(b)(1) presents an entirely different statute than the one that confronted the courts in *Garcia* and *Henderson*. Whereas the Michigan statute expressly sets forth the elements of a fraud-on-the-FDA theory to avoid a defense, §82.007(b)(1) merely sets forth a category of evidence that is admissible to defeat a "rebuttable presumption":

> [T]he defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;

This provision does not codify a fraud-on-the-FDA theory. Notably absent is the provision in the Michigan statute that the jury must put itself into the FDA's shoes to determine what effect the withheld or misrepresented evidence would have had on the approval of the drug. Simply, this provision does not come within the holding of *Buckman*.

What then do we make of *Kobar*? Although *Kobar* is distinguishable on other grounds, as Plaintiff discusses below, Plaintiff must acknowledge that there are elements of that holding that affect the arguments in this case. Specifically, the Arizona statute at issue in *Kobar* did not set forth the elements of a fraud-on-the-FDA cause of action, but required merely that the evidence be

"material and relevant," as does TEX.CIV.PRAC. & REM. CODE §82.007(b)(1); yet the district court held that federal law, per *Buckman*, preempted its application. There are two primary flaws in the *Kobar* court's reasoning.

First, it is important to note that the Arizona statute at issue does not immunize the defendant from any claim for actual damages. The Arizona statute addressed only claims for punitive damages. Certainly a statute that allows compensatory recovery, but puts severe limitations on the recovery of punitive damages, merits considerably less scrutiny than one that forecloses compensatory recovery. Nonetheless, the *Kobar* court wrongly viewed both the Michigan statute and *Garcia* as dealing exclusively with punitive damages when using them as compelling authority. *E.g.*, "Michigan, like Arizona, immunizes drug manufacturers from punitive damage liability in actions based on injuries from FDA-approved drugs," 378 F.Supp.2d at 1172; "the plaintiff in *Garcia* had to prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under Michigan law," *Id*.

Perhaps because the court viewed the issue as solely one of punitive damages, the district court then made a leap in logic that is simply unsupported by the express terms of the Arizona statute: "The present case, in contrast, . . . involves a state statute which immunizes drug manufacturers from punitive damages liability *unless* the plaintiff can prove fraud on the FDA." 378 F.Supp.2d at 1172. Neither the Arizona statute nor TEX.CIV.PRAC. & REM. CODE §82.007(b)(1) requires the plaintiff to prove fraud on the FDA, notably because neither statute requires the crucial element of reliance, *i.e.*, that the FDA would have acted differently had the information been provided. With all due respect to the district court, its holding that the Arizona statute required proof of fraud on the FDA as an "essential element" of the plaintiff's proof is simply mistaken.

The district court's mistake in this regard allowed it to shoehorn the Arizona statute into the *Buckman* preemption holding. Because of this mistake, the court in *Kobar* refused to follow the case authorities that have properly recognized that, while *Buckman* precludes a cause of action that depends on fraud on the FDA, it does not preclude evidence that a drug manufacturer has withheld evidence from, or misrepresented evidence to, the FDA if this evidence is not offered to establish fraud on the FDA. *E.g.*, *Eve v. Sandoz Pharm. Corp.,* 2002 WL 181972 (S.D. Ind. 2002); *Caraker v. Sandoz Pharm. Corp.,* 172 F.Supp.2d 1018 (S.D.Ill.2001); *Globetti v. Sandoz Pharm. Corp*., 2001 WL 419160 (N.D. Ala. 2001)("The exclusive focus of the Supreme Court's analysis is on the "fraud-on-the-agency" theory and its unavoidable conflict with the agency's own enforcement schemes."); *Dawson ex rel. Thompson v. Ciba-Geigy Corp., USA,* 145 F.Supp.2d 565 (D.N.J. 2001); *Bryant v. Hoffmann-La Roche, Inc.,* 262 Ga.App. 401, 585 S.E.2d 723 (2003).

The holding of the cases that the *Kobar* court ignored also dovetail with the Supreme Court's own writing in *Buckman* itself:

> [I]t is clear that the *Medtronic* arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. *See* 518 U.S., at 481, 116 S.Ct. 2240. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.
>
> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case.

531 U.S. at 352-53. Neither the Arizona statute nor TEX.CIV.PRAC. & REM. CODE §82.007(b)(1) requires proof of fraud on the FDA, notably because neither requires any showing of what the FDA

would have done if the evidence had not been withheld nor misrepresented. Plaintiff's cause of action relies on long-established state tort law, not on federal regulations.

In fact, TEX.CIV.PRAC. & REM. CODE §82.007(b)(1) is even one more step removed from the analyses of *Kobar*, *Garcia* and *Henderson*. The Michigan statute at issue in *Garcia* and *Henderson* "immunizes drug manufacturers from liability," 385 F.3d. at 963. The language of that statute and the holdings in *Garcia* and *Henderson* make clear that the courts viewed the Michigan statute as a substantive defense to the cause of action. Likewise, the Arizona statute at issue in *Kobar* provides a defense to a claim of punitive damages (although requiring very different proof than the Michigan statute, as discussed above). In contrast, TEX.CIV.PRAC. & REM. CODE §82.007(b)(1) does not provide a substantive defense, but merely a "rebuttable presumption" – an evidentiary presumption that the claimant can rebut with certain categories of evidence. Even if *Kobar* were correct in its holding that evidence that a drug manufacturer had withheld "material and relevant" evidence somehow equated to a fraud on the FDA theory for the purpose of establishing a substantive defense, even though the statute requires no proof of reliance, the case at bar involves an evidentiary presumption which the claimant can expressly rebut. The fact that this is an evidentiary presumption rather than a "cause of action" or a defense takes TEX.CIV.PRAC. & REM. CODE §82.007(b)(1) even further from the scope of *Buckman*. Plaintiffs are not required to establish fraud on the FDA, but merely to introduce evidence to rebut an evidentiary presumption. *Buckman* does not preempt §82.007(b)(1).

B. Preempt One – Preempt All. As noted above, Wyeth's primary argument is that *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001) preempts §82.007(b)(1). Its necessary corollary, which flies in the face of, not only common sense, but also the severability provisions of HB 4 and the Texas Government Code, is that *Buckman* does **not** preempt §82.007(a).

The Texas statutes' severability language precludes severance in this case. If, notwithstanding the arguments above, this Court concurs with *Garcia, Henderson* and *Kobar*, and determines, as a matter of *federal* law, that *Buckman* does, indeed, preempt §82.007(b)(1), then it must decide whether §82.007(a) is also precluded. This is almost certainly a question of state law.

IF the Legislature's statutory language is invalid, *e.g.*, via a determination of unconstitutionality, federal preemption, etc., then, what is the Legislature's intent with regard to other portions of the statute? In parallel statutory language, both HB 4 and the Texas Government Code define the scope of invalidity as follows:

> the invalidity does not affect other provisions or applications . . . **that can be given effect without the invalid provision** or application.

Wyeth brief at Fns 11-13.

There are easy examples of this. For example, absent the decision by the voters of Texas to cede away portions of their Open Courts' constitutional protection, the medical malpractice caps in HB 4 would clearly have been unconstitutional. *Lucas v. United States*, 757 S.W.2d 687 (Tex. 1988). But, obviously, this constitutional invalidity would have absolutely nothing to do with a drug company's liability. Therefore, all of §82.007 would be totally untouched by the constitutional invalidity.

But, does this Court really believe that, when the Legislature set forth five different ways to rebut the presumption of no liability, that it really meant that, preemption invalidity of subsection 82.007(b)(1) notwithstanding, Wyeth could **still** have a "get out of jail free" card? Does that make any sense whatsoever? Of course not!

> The test for severability in the absence of an express severability clause is one of legislative intent. We have stated the rule to be that where a statute contains an unconstitutional provision, and another which, if standing by itself, would be valid, the latter will be given effect, provided they are so clearly independent of each other that the

> court can say that the Legislature would have passed it if the former had been omitted. On the other hand, if they be so connected one with the other, or so dependent one upon the other, that *831 it is apparent that the Legislature would not have passed the act, except as a whole, then the entire statute must fall.

Association of Texas Professional Educators v. Kirby, 788 S.W.2d 827, 830-31 (Tex. 1990). The illogic of passing one section without another illustrates that the Legislature in this case must have intended that the entire statute would either stand or fall in the face of a *Buckman* challenge. The absence of a savings clause, with which both the Texas Legislature and the Texas Supreme Court were well familiar, underscores this obvious legislative intent. *See Rose v. Doctors Hospital*, 801 S.W.2d 841 (Tex. 1990)(Phillips, C.J. dissenting).

Because there is no hint of a legislative intent to throw the baby out with the bath water, IF *Buckman* preempts part of 82.007, it must necessarily preempt the whole of that section.

C. Wyeth has Withheld Foreign Suicides and Suicide Attempts from the FDA. In a short paragraph on page 21 of its Brief, Wyeth argues that "plaintiff cannot make the showing" required by the Texas statute. In her deposition in this case, former Wyeth VP Dr. Wendy Stephenson testified that, because Wyeth deems suicidality as being "labeled," it does not report either foreign suicides or suicide attempts, by patients taking Effexor, to the FDA. Exhibit I.

Obviously this information is both "material and relevant" and "causally related" to Martin Ackermann's death. Consequently, the showing required by §82.007(b)(1) can be made.

III. BECAUSE MARTIN ACKERMANN SOUGHT TO ACQUIRE MEDICAL SERVICES BY PURCHASE, NEITHER PLAINTIFF'S WARRANTY CLAIMS NOR DTPA[23] CLAIMS ARE SALE DEPENDENT

In clever parallel arguments, Wyeth contends that, because Dr. Sonn provided Martin Ackermann with free Effexor samples, there are no viable warranty claims. Amazingly, the one case in the country that seems to say that hails from the Southern District of Texas. In *Allen v. Ortho Pharmaceuticals Corp*., 387 F.Supp. 364 (S.D.Tex. 1974) the court reached this result. In the 32 years since it was handed down, *Allen* has been cited one and only one time. It was 1977, and the citation was from another judge in the Southern District. *Roberts v. General Dynamics, Convair Corp*., 425 F.Supp. 688 (S.D.Tex. 1977). Chief Judge Singleton pointed out that "In the landmark case of *Jacob E. Decker & Sons, Inc. v. Capps*, 139 Tex. 609, 164 S.W.2d 828 (1942), the Texas Supreme Court held the manufacturer of a food product liable to an injured ultimate consumer despite the absence of a direct contractual relationship. The court emphasized that the concept of warranty is variable, grounded as soundly in public policy as in traditional contractual relationships: The fact . . . that liability may be sustained in some cases because of a breach of a contractual warranty does not argue against the sustaining of liability on the ground herein adhered to warranty imposed by law as a matter of public policy." *Id.* He also pointed out that the same rationale for rejecting privity extends to strict products liability theories, under *McKisson v. Sales Affiliates, Inc.*, 416 S.W.2d 787 (Tex.1967) and its progeny. Tellingly, he then wrote: "This conclusion is equally valid under the implied warranty provision of the Texas Business & Commerce Code. To waive the privity requirement in a personal injury case where the warranty arises in 'tort' while retaining it

[23] Wyeth also argues that DTPA claims do not survive Martin Ackermann's death. There is case law to support that argument. However, there is a split of Texas authority on point. Therefore it would be premature for this Court to grant summary judgment at this stage on this ground. The Court can revisit that issue with counsel at the time of trial.

where the warranty arises in 'contract' is to perpetuate a formalistic distinction at the expense of the public policy considerations repeatedly emphasized by the Texas Supreme Court."

As her attached Affidavit proves, Rozlyn Ackermann and her husband sought to acquire medical services from Dr. Sonn. Exhibit J. And they paid for them. The fact that he started Marty Ackermann on free professional samples from Wyeth defeats neither the warranty claims nor the DTPA claims.

The Texas Supreme Court has written that the essential ultimate factual inquiry for a breach of implied warranty claim is essentially the same as for any other product "defect," and the pattern jury instructions state the inquiry simply and succinctly as follows:

> A "defect" means a condition of the product that renders it unreasonably dangerous. An "unreasonably dangerous" product is one that is dangerous to an extent beyond that which would be contemplated by the **ordinary user** of the product, with the **ordinary knowledge** common to the community as to the product's characteristics.

Texas PJC §71.3. Because there is ample evidence that Effexor is much more dangerous, *viz. a viz.* the risk of suicide, than would be expected by the "ordinary user" of this product, Wyeth is liable under a breach of implied warranty theory, free samples notwithstanding.

IV. SUMMARY JUDGMENT IS APPROPRIATE ON THE FRAUD AND MISREPRESENTATION THEORIES

Although it is unclear whether reliance is an element of a Restatement misrepresentation theory, because the record is clear that Dr. Sonn remembers absolutely nothing that any of his Wyeth sales representatives told him about the drug, Plaintiff agrees that summary judgment on these two theories is appropriate.

CONCLUSION

Summary judgment is a useful tool under the right circumstances. Unfortunately, however, the filing of motions seeking same has become *de rigeur* tactics for the pharmaceutical defense lawyer. For the foregoing reasons, we submit that, with the exception of the fraud and misrepresentation theories, in this case, Wyeth's motion should be denied.

Respectfully submitted,

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Certificate of Service

I hereby certify that a copy of the above pleading was served on all counsel of record, as follows, on this 24th day of July, 2006.

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